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10/716,410	11/20/2003	Roger Rozot	016800-557	5557

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EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/716,410

Applicant(s)

ROZOT ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-7, 9-23, 36, 38-44, 46-49 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 21 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, 11-20, 23, 36, 38-44, 46-47, 49 and 57-60 is/are rejected.
- 7) ☒ Claim(s) 22 and 53-56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 1, 2, 4-7, 9-23, 36, 38-44, 46-49 and 53-60 are pending in this application. Claims 3, 8, 24-35, 37, 45 and 50-52 stand cancelled.

#### ***Election/Restrictions***

Applicant's election with traverse of Formula (I) wherein R1 and R2 is hydrogen and the other is saturated, linear 01-020 alkyl (ethyl) substituted with T1 which is SR6 wherein R6 is saturated, linear C1-C20 alkyl substituted with R2 which is a furan ring; one of R3 and R5 is hydrogen and the other is A, which is a saturated, linear C1-C20 alkyl substituted with at least one T5 which is/are halogen; and R4 is phenyl, in the reply filed on 7/25/06 is acknowledged. Further applicant elects head hair; salicylic acid derivatives as the second active agent; aminexil as the second agent; and compound 1 of claim 22. Applicant traverses the rejection and does not provide any reasons for the traversal. Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4-7, 11-20, 22, 23, 36, 38- 44, 46-47, 49 and 53-60 are directed to the elected species. Claims 9-10, 21, 48 are withdrawn.

#### ***Claim Rejections - 35 U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, 11-20, 23, 36, 38- 44, 46-47, 49 and 57-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reasonable subgenus as exemplified in claim 22, wherein, for example, the following chemical properties

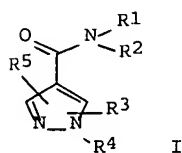
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are reasonably maintained: total molecular size; charge distribution; hydrophobicity; polarity; hydrophilicity; and hydrogen bonding, does not reasonably provide sufficient enablement to one of ordinary skill in the art as to which of the seemingly infinite number of derivatives disclosed across the entire scope of the extremely generic claims would in fact actually induce hair growth and hair density by inhibition of 15-PGDH, without an undue amount of experimentation.

Therefore, the specification does not enable one skilled in the relevant art to which the invention pertains to practice (i.e., use) the invention commensurate in scope with the aforementioned rejected claims. Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

### *Nature of the Invention*

The instant claims are directed to a method inducing hair growth and hair density and/or reducing hair growth by administering a compound with formula (I):



Note formula (II) of claim 13 is encompassed by formula (I). Applicant attributes the growth of hair and reduction of hair loss to the inhibition of 15-PGDH by the pyrazolocarboxamide compounds.

***The Scope or Breadth of the Claims***

The instant claims are directed to a method inducing hair growth and hair density and/or reducing hair growth by administering a pyrazolcarboamide compound (formula I) that is substituted with a seemingly infinite number of chemical moieties, which thereby inhibits 15-PGDH.

***Guidance of the Specification***

The guidance provided by the specification speaks on administering pyrazolcarboxamide compounds to induce hair growth or reducing hair loss by inhibiting 15-PGDH but does not discuss the instant structure-activity relationships with respect to how the substitution of the core with various particular chemical moieties directly effects the bioactivity and inhibitory properties. Furthermore, the specification teaches pyrazolcarboxamides with various substituents do no have the ability of inhibiting 15-PGDH. Thus, it can readily be seen from applicant's own admission that properties of the respective compound varies with the substituents.

***Working Examples***

The specification exemplifies only 8 compounds out of the seemingly infinite number of derivatives claimed in the independent claims.

***The Level of Predictability in the Art***

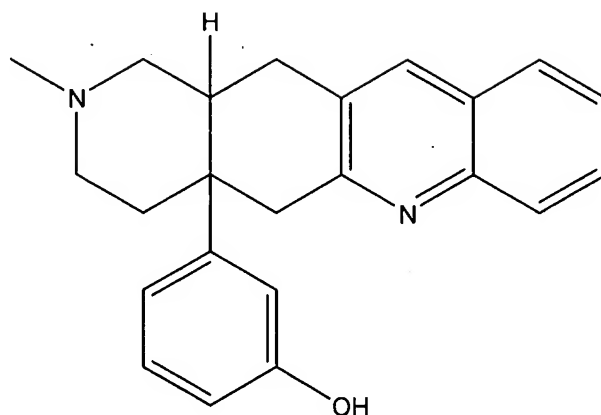
Drug discovery is an extremely tedious, laborious and expensive. The basis for the extraordinary degree of unpredictability associated with drug discovery in particular, can be attributed to the exquisite stereospecificity that exists between an enzyme and its corresponding substrate, or a ligand and its corresponding receptor. This principle is particularly evidenced by

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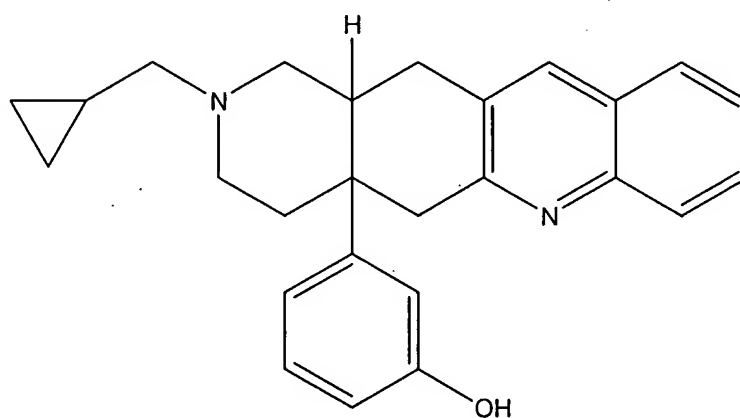
the following examples previously documented in the chemical and pharmaceutical scientific literature and prior art.

The unpredictable and surprisingly dramatic effects that can result from a simple modification of even a single pendant chemical moiety of an active core compound is strikingly apparent when considering opioid analgesics, for example. Upon simple substitution of the N-methyl group of TAN-67 (illustrated below), which is a highly selective and potent nonpeptidic  $\delta$  opioid receptor *agonist*, with either a methylcyclopropyl group, or even an allyl group for that matter, TAN-67 is subsequently converted into a  $\delta$  opioid receptor *antagonist*. Goodman & Gilman's The Pharmacological Basis of Therapeutics, 9<sup>th</sup> Ed., McGraw-Hill, NY, page 549 (1996); and Nagase, H., et al., The Pharmacological Profile of  $\delta$  Opioid Receptor Ligands, (+) and (-) TAN-67 on Pain Modulation, Life Sciences, Vol. 68, pp. 2227-2231 (2001).

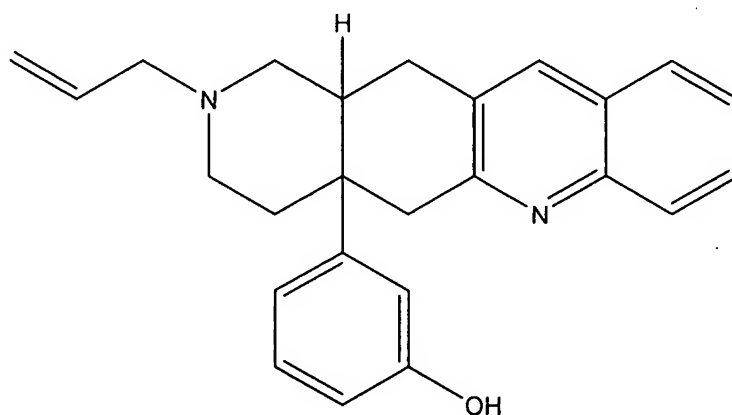
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3-(1,2,3,4,4a,5,12,12a-octahydro-2-methylpyrido[3,4-*b*]acridin-4a-yl)phenol (a.k.a. TAN-67)  
delta opioid receptor *agonist*



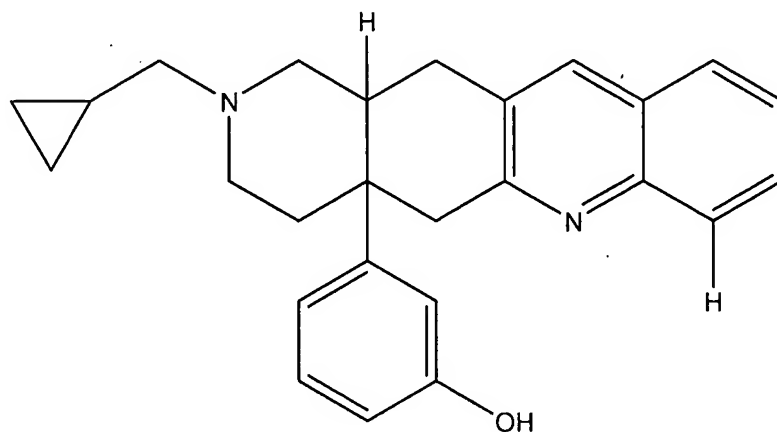
3-(2-(cyclopropylmethyl)-1,2,3,4,4a,5,12,12a-octahydro-2-methylpyrido[3,4-*b*]acridin-4a-yl)phenol  
delta opioid receptor *antagonist*



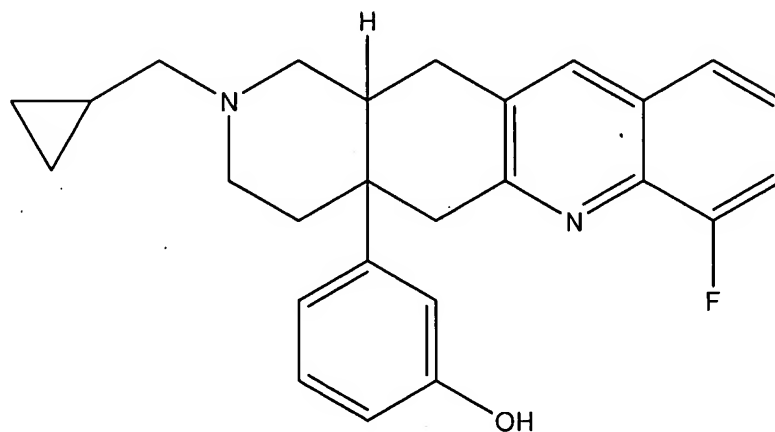
3-(2-allyl-1,2,3,4,4a,5,12,12a-octahydro-2-methylpyrido[3,4-*b*]acridin-4a-yl)phenol  
delta opioid receptor *antagonist*

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In addition, if one were to modify the methylcyclopropyl substituted TAN-67, which is a  $\delta$  opioid receptor *antagonist*, by substituting a fluorine atom for a hydrogen atom on the aromatic phenyl ring near the quinoline nitrogen (illustrated herein below), the  $\delta$  opioid receptor *antagonist* would be converted into a *partial*  $\delta$  opioid receptor *agonist*, even though fluorine and hydrogen have the same atomic radius.



3-(2-(cyclopropylmethyl)-1,2,3,4,4a,5,12,12a-octahydropyrido[3,4-*b*]acridin-4a-yl)phenol  
delta opioid receptor *antagonist*

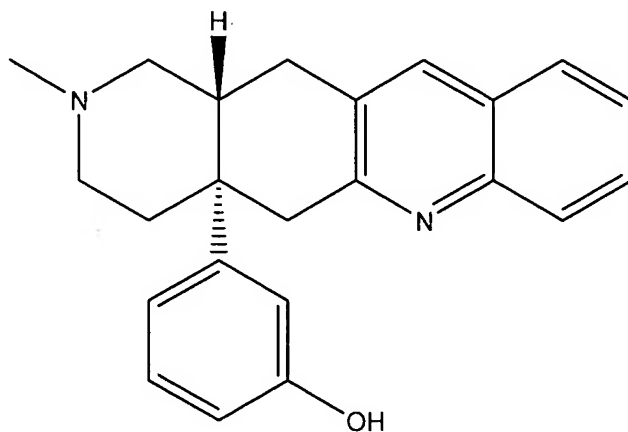


3-(2-(cyclopropylmethyl)-7-fluoro-1,2,3,4,4a,5,12,12a-octahydropyrido[3,4-*b*]acridin-4a-yl)phenol  
*partial* delta opioid receptor *agonist*

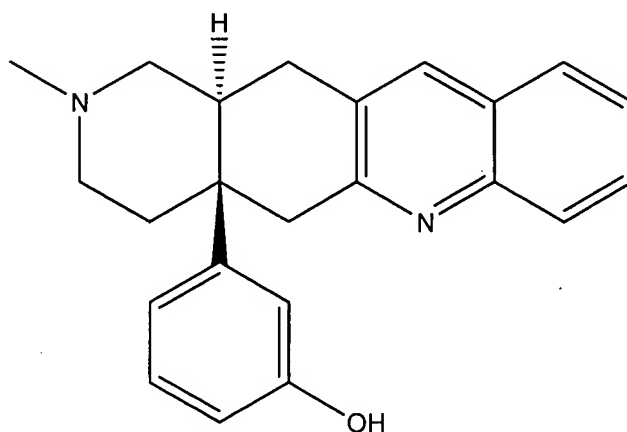


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Moreover, by simply selecting from different stereoisomers of TAN-67 (illustrated below), one could go from (-)-TAN-67, which is a potent antinociceptive (analgesic), to (+)-TAN-67, which not only fails to exhibit analgesic properties, but astonishingly induces pain-like nociceptive behavior, such as scratching and biting.



3-((4a*S*,12a*R*)-1,2,3,4,4a,5,12,12a-octahydro-2-methylpyrido[3,4-*b*]acridin-4a-yl)phenol  
(a.k.a. (-)-TAN-67)  
*potent antinociceptive (analgesic)*



3-((4a*R*,12a*S*)-1,2,3,4,4a,5,12,12a-octahydro-2-methylpyrido[3,4-*b*]acridin-4a-yl)phenol  
(a.k.a. (+)-TAN-67)  
*induces pain-like nociceptive behavior*

Based on the aforementioned discussion regarding opioid analgesics, it is readily apparent that minor, seemingly trivial, modifications to the core compound can create profound changes in biological activity. The paramount and unpredictable ramifications that minor structural modifications to the core compound can have on the biological activity of opioid receptors are equally pertinent and applicable to all drugs and all receptor agonists and antagonists. Therefore, this example illustrates the exquisite stereospecific characteristics associated with all therapeutics and their reactions in vivo. Further, the example above demonstrates that a simple substitution of a halogen with a hydrogen without changing the core compound, changes the properties of the compound. In instant application, the generic broad compound claimed in the independent claim have R groups that may have varied with a broad spectrum of substituents including halogens and hydrogens. However, clearly it can be seen from the above example that a different reactivity is rendered depending on even a seemingly simple modification.

A final example evidencing unpredictability in association with drug discovery is illustrated by the following research efforts, which utilized combinatorial chemistry techniques. Combinatory chemistry is generally defined as a branch of applied chemistry concerned with the rapid synthesis and screening of large numbers of different but related chemical compounds generated from a known building block in order to recover new substances optimally suited for a specific function. In this particular example, combinatorial chemistry techniques were implemented in an effort to identify more efficacious inhibitors of cathepsin D, which is an aspartyl protease. Kick, E.K., et al., Structure-Based Design and Combinatorial Chemistry Yield Low Nanomolar Inhibitors of Cathepsin D, *Chemistry & Biology*, Vol. 4, No. 4, pp. 297-307

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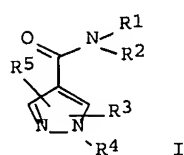
(1997). More specifically, combinatorial libraries were designed and created around the synthesis and subsequent structural derivatization of a stable mimetic building block of the tetrahedral intermediate of amide hydrolysis, namely (hydroxyethyl)amine isostere, which was an already known inhibitor of aspartyl proteases. Of the 2,000 derivatives that comprised the resultant and expansive library, over 90% of the synthesized compounds were biologically *inactive*. Since more than 90% of the synthesized compounds generated in the aforementioned combinatorial library, which was designed and created around the structural derivatization of a stable and efficacious building block or active core, were in fact biologically *inactive*, one of ordinary skill in the art would have a justifiably sound reason to doubt that even a reasonable fraction, much less a simple majority, of the chemical derivatives disclosed across the entire scope of the tremendously broad and extremely generic claims would in fact possess desired biological activity. With such a high degree of unpredictability in the drug discovery art, the applicant bears a greater burden of providing adequate support in the specification so as to guide one of ordinary skill in the art through the generic maze that is commensurate in scope with the claims.

With regard to the instant substituted pyrazolecarboxamide, The examiner further cites Bogoslovskaia SI et al. Effect of the structural characteristics of the alkyl derivatives of imidazole and pyrazole dicarboxylic acid diamides on body respiratory functions. Farmakologiya i toksikologiya, (1980 Nov-Dec) Vol. 43, No. 6, pp. 667-71. Bogoslovskaia et al disclose :

It has been ascertained that alkyl derivatives of imidazolecarboxylic acid diamides produce different effect on respiration and acid-base balance (ABB) of animal body. Antipheine and ethymisole stimulate respiration and change ABB. Ethirazol does not affect respiration, producing only insignificant changes in the respiratory component of ABB. Differences in the biological activity of the test drugs may be related to the structure or position of the alkyl radical in the heterocyclic ring.

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The examiner cites US 5,498,624 and US 5,965,579. US '624 is directed to a pyrazolecarboxamide derivative that are useful as plant fungicides. US '579 is directed to pyrazolecarboxamide derivatives that are useful in pharmaceutical for due to their affinity to neurotensin receptors. Thus, it can readily be seen that the properties of a compound varies with the substituents on the core. Although US '624 and US '579 share the same core,



the properties displayed by each respective compound is markedly different due to the substituents.

### ***The Amount of experimentation Necessary***

One of ordinary skill in the art would not be able to reasonably predict or anticipate the ramifications that minor structural changes, with respect to different stereoisomers of a core compound, can have on the bioactive properties thereof. Moreover, the instant application is directed to a substituted pyrazolecarboxamide and a seemingly infinite number of potential chemical moieties without any discussion on the instant structure-activity relationships with respect to how the substitution of the core with various particular chemical moieties directly effects the bioactivity and inhibitory properties. Based on the breathtaking scope of the claimed invention and the extraordinary degree of unpredictability associated therewith, a skilled artisan would quickly become overburdened with the daunting task of attempting to accurately predict which of the countless number of derivatives, if synthesized, would actually reduce hair loss and

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increase hair growth by the inhibition of 15-PGDH. Without more, such as scientific data illustrating structure-activity relationships with respect to how the actual substitution of the generic pyrazolecarboxamide with various particular chemical moieties directly impacts the selective inhibition against 15-PGDH, one of ordinary skill in the art would not be able to extrapolate, without an undue amount of experimentation, which of the exponential number of derivatives disclosed across the entire breadth of the tremendously broad claims would in fact actually inhibit 15-PGDH thereby increasing hair growth. As a result, a skilled artisan seeking to practice the extraordinary scope of the claimed subject matter would be required to perform an extraordinary amount of trial and error experimentation (i.e., inhibition assays). Therefore, one of ordinary skill in the relevant art would not be able use the invention commensurate in scope with the aforementioned rejected claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

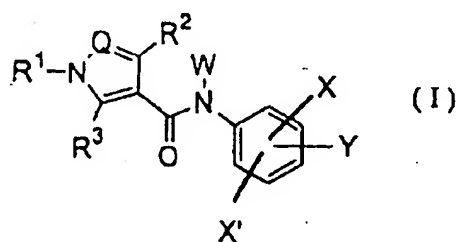
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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**Claims 1-2, 4-7, 11-20, 23, 36, 38-40, 42, 47, 49, 57 are rejected under 35 U.S.C.**

**103(a) as being unpatentable over EP 1176140.**

EP teaches amide compound and their medical uses. The compound formula:



wherein R<sup>1</sup> is substituted aryl, heteroaryl and the like, R<sup>2</sup> and R<sup>3</sup> are hydrogen, alkyl, halogen, hydroxyl group and the like, Q is N, CH and the like, W is hydrogen, alkyl, hydroxycarbonylalkyl and the like, X is halogen, cyano, nitro, amino and the like, X' is hydrogen, halogen, cyano, nitro, and Y is alkyl, hydroxyl group, alkoxy, mercapto and the like and a salt thereof, and a medicine containing the said compound. See abstract.

The compound may be utilized to treat various autoimmune disease such as rheumatoid arthritis, systemic lupus erythematosus, nephrotic syndrome lupus, Hashimoto's struma, multiple sclerosis, myasthenia gravis, type I diabetes, type II adult onset type diabetes mellitus, uveitis, nephrotic syndrome, steroid-dependent and steroid resistant nephrosis, pustulosis palmoplantaris, allergic encephalomyelitis, glomerular nephritis. Moreover, the compounds may be used for the treatment of inflammatory, proliferative and superproliferative dermatosis, onset on the skin of immunity-mediated diseases, such as psoriasis, psoriatic arthritis, atopic eczema (atopic dermatitis), contact dermatitis, eczematous dermatitis, seborrheic dermatitis, lichen planus,

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pemphigus, bullous pemphigoid, epidermolysis bullosa, urticaria, vascular edema, angitis, erythema, eosinophilic increase of skin, acne, alopecia areata, eosinophilic fasciitis and atherosclerosis EP teaches the compounds prevent epilation, forms hair germ and/or produces and grows hair, and can be used for recovery of hair by treating female or male pattern alopecia and senile alopecia. see page 36, [0070].

EP teaches the compounds have a synergistic action when combined with other pharmaceutical agents. [0076]. The compounds may be admixed with a pharmaceutically acceptable carrier (e.g., excipient, binder, disintegrator, corrective, corrigent, emulsifier, diluent, solubilizer and the like) to give a pharmaceutical composition or pharmaceutical preparation, which is formulated into tablet, pill, capsule, granule, powder, syrup, emulsion, elixir, suspension, solution, injection, infusion, eye drop, eye ointment, suppository, ointment, lotion and the like and administered orally or parenterally. See [0077]. The dose of the compound is determined in consideration of the age, body weight, general health condition, sex, diet, administration time, administration method, clearance rate, combination of drugs, level of disease for which the patient is under treatment and other factors. Typically the dosage ranges from about 0.01 1000 mg/person/day, preferably 0.01 500 mg/person/day. [0083].

Although EP suggest the use of the compounds for treating alopecia, a skilled artisan would not have immediately envisaged the use of the compounds in treating alopecia.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the compounds taught in EP for the treatment of hair loss. One would have been motivated to do so since EP teaches the compounds are useful for treating various conditions including alopecia and increasing hair growth. Therefore, the instant

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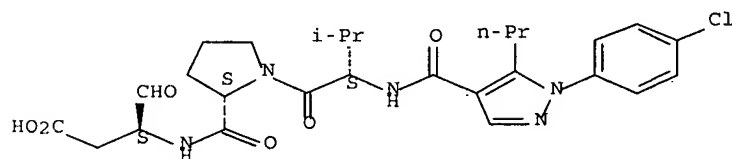
methodology is considered prima facie obvious since EP is suggestive of the instant methodology.

With regard to claim 12, note that the composition is taught to be applied to the same population (patients suffering from alopecia) and to the same area with the same compound recited in the independent claims, thus the preservation of prostaglandin activity will necessarily occur.

**Claims 1-2, 4-7, 11-20, 23, 36, 38-40, 42, 47, 49, 57 are rejected under 35 U.S.C.**

**103(a) as being unpatentable over WO 99/47545.**

WO teaches inhibitors of caspases. Several compounds are taught including:



for various diseases such as autoimmune diseases, proliferative diseases, respiratory diseases, skin diseases, etc. The treatment of alopecia is taught among the various disorders. Dosage levels are 0.1-100mg per day. See page 45. Topical administration is taught and the composition may be in the form of a lotion, cream, or ointment and the composition contains various additives including water, glycols, mineral oil, etc. See page 39. WO teaches the use of other pharmaceutical agents with the caspase inhibitors such as anti-inflammatory agents, lipoxygenase inhibitors, etc. depending on the disease to be treated. See pages 39-40.

Although WO suggests the use of the compounds for treating alopecia, a skilled artisan would not have immediately envisaged the use of the compounds in treating alopecia.



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However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the compounds taught in WO for the treatment of alopecia. One would have been motivated to do so since WO teaches the compounds are useful for treating various conditions including alopecia. Therefore, the instant methodology is considered prima facie obvious since WO is suggestive of the instant methodology.

With regard to claim 12, note that the composition is taught to be applied to the same population (patients suffering from alopecia) and to the same area with the same compound recited in the independent claims, thus the preservation of prostaglandin activity will necessarily occur.

**Claims 43-44, 46, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1176140 or WO 99/47545 respectively in view of Bradbury et al (6,124,362).**

The teachings of EP and WO have been set forth above.

Although both EP and WO teach the use of various active agents that may be used with the compounds, the reference do not teach the instant aminexil and salicylic acid derivatives.

Bradbury teaches a method for regulating hair growth using terpenes. See abstract. Bradbury teaches the use of vasodilators including minoxidil and minoxidil derivatives such as aminexil. See column 22, line 60; column 23, lines 5-4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP or WO respectively and Bradbury and further utilize aminexil with the compounds described in EP or WO respectively. One would have been motivated to further utilize aminexil with an expectation of success since Bradbury teaches aminexil is a hair growth agent and both WO and EP teach the compounds may be combined

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with other pharmaceutical agents. Thus, the selection of the additional pharmaceutical would have been dependent on the disorder the compounds are utilized to treat. Therefore, if a skilled artisan desired to treat alopecia as suggested by EP and WO respectively, then the secondary pharmaceutical would have been another hair growth agent for its additive effect.

**Claims 41 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1176140 or WO 99/47545 respectively in view of Rosenbaum et al (5,443,823).**

The teachings of EP and WO have been set forth above.

Although both EP and WO teach the use of various active agents that may be used with the compounds, the reference do not teach the instant salicylic acid derivatives.

Rosenbaum teaches a method for inducing and stimulating the growth of hair using instant salicylic acid derivative. See examples and abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP or WO respectively and Rosenbaum and further utilize the instant salicylic acid derivative with the compounds described in EP or WO respectively. One would have been motivated to further utilize salicylic acid derivative with an expectation of success since Rosenbaum teaches salicylic acid derivative for hair growth and both EP and WO teach the compounds may be combined, including anti-inflammatory agents, with other pharmaceutical agents. Thus, the selection of the additional pharmaceutical would have been dependent on the disorder the compounds are utilized to treat. Therefore, if a skilled artisan desired to treat alopecia as suggested by EP and WO respectively, then the secondary pharmaceutical would have been another hair growth agent for its additive effect.

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*Claim Objections*

Claims 22 and 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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